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EXAMINER

KING, FELICIA C

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,501	Applicant(s) HUETING, ULCO	
	Examiner FELICIA C. KING	Art Unit 1784	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/22/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 3, 4, 6, 7, 11, 13, 14, 17, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 1 recites the limitation "the lactose" in line 2 of claim 1. There is insufficient antecedent basis for this limitation in the claim.

4. Claim 3 recites the limitation "the enzymatic hydrolysis" in line 2 of claim 3. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 4 recites the limitation "the initial product" in line 3 of claim 4. There is insufficient antecedent basis for this limitation in the claim.

6. Regarding claim 6, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

7. Regarding claim 7, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

8. Claim 11 recites the limitation "the milk whey fermentate" in lines 3 and 4 of claim 11. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 13 recites the limitation "the enzymatic hydrolysis" in line 2 of claim 13. There is insufficient antecedent basis for this limitation in the claim.

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10. Claim 14 recites the limitation "the initial product" in line 2 of claim 14. There is insufficient antecedent basis for this limitation in the claim.

11. Regarding claim 17, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

12. Regarding claim 19, the phrase "and/or" is used multiple times regarding the inclusion of additional ingredients. This renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. **Claims 1, 5-11, and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Rodgers et al. (US 2,930,696).**

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Regarding Claims 1, 5, 8: Rodgers discloses a concentrated food product formed from cheese whey that has at least 90% of its lactose converted to lactic acid due to lactic acid fermentation [col. 4, lines 3-27] with *L. bulgaricus*, *L. acidophilus*, *Streptococcus lactis*, or *S. thermophilus* as the lactic acid bacteria [col. 3, lines 17 -23]. Rodgers also teaches that the concentrated mixture contains an additional .4% propionic acid (organic acid) [col. 4, lines 55-58]. Rodgers does not explicitly disclose that the ratio of added organic acid to lactic acid is 1:30 to 8:1. Rodgers does disclose that 95% of the 7 % lactose present, in the cheese whey, is converted to lactic acid [col.4, lines 15-27] which is equivalent to roughly 6.3% lactic acid in the concentrate and also discloses that .4% propionic acid is added to the concentrate for mold/bacteria inhibitory effect. Based upon percentage weight, for every 16.75% lactic acid in the concentrate, 1% propionic acid would have been added.

At the time of the invention it would have been obvious to one of ordinary skill in the art to add the organic acid in proportion to the lactic acid in an amount sufficient to provide a mold and bacteria inhibitory effect, while providing flavor from propionic acid, and while keeping the flavoring properties of lactic acid and since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272.

Regarding Claim 6: Rodgers discloses drying to a solids content (dry matter content) of 55% [col. 4, lines 50-53].

Regarding Claim 7: Rodgers discloses maintaining the product at a pH of about 5.6 [col. 3, lines 23-25].

Regarding Claim 9: Rodgers discloses adding 0.4% propionic acid to the product [col.4, lines 55-58].

Regarding Claim 10: Rodgers discloses adding vitamins to the product [col. 4, lines 36-38].

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Regarding Claims 11, 16, 18, and 21: Rodgers discloses a method of making a whey product containing converted lactose that has at least 90% of its lactose converted to lactic acid due to lactic acid fermentation, with *L. bulgaricus*, *L. acidophilus*, *Streptococcus lactis*, or *S. thermophilus* [col. 3, lines 17 -23], concentrating the fermented mixture [col. 4, lines 3-27]. Rodgers also teaches that the concentrated mixture contains an additional .4% propionic acid (organic acid) [col. 4, lines 55-58]. Rodgers does not explicitly disclose that the ratio of added organic acid to lactic acid is 1:30 to 8:1 (claim 11). Rodgers does disclose that 95% of the 7 % lactose present, in the cheese whey, is converted to lactic acid [col.4, lines 15-27] which is equivalent to roughly 6.3% lactic acid in the concentrate and also discloses that .4% propionic acid is added to the concentrate for mold/bacteria inhibitory effect. Based upon percentage weight, for every 16.75% lactic acid in the concentrate, 1% propionic acid would have been added.

At the time of the invention it would have been obvious to one of ordinary skill in the art to add the organic acid in proportion to the lactic acid in an amount sufficient to provide a mold and bacteria inhibitory effect, while providing flavor from propionic acid, and while keeping the flavoring properties of lactic acid and since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272.

Further regarding claim 21, the concentrate is storage stable by virtue of the inclusion of propionic acid as a mold and bacteria inhibitor.

Regarding Claim 17: Rodgers discloses maintaining the product at a pH of about 5.6 [col. 3, lines 23-25].

Regarding Claim 19: Rodgers discloses adding vitamins before further concentrating [col. 4, lines 36-41].

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16. **Claims 2-4 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodgers et al. (US 2,930,696) in view of Casella (US 4,492,712) and Czarnetsky (US 2,904,437).**

Regarding Claims 2-4: Rodgers discloses fermented whey and the conversion of lactose to lactic acid as discussed above. Rodgers does not disclose converting the lactose by hydrolysis or enzymatic hydrolysis, or that 25% to 99% of the lactose is converted respectively. Casella discloses substituting non fat dry milk with hydrolyzed whey [col.1, lines 50-56, col. 3, lines 15-23. Casella discloses that the lactose in the whey is hydrolyzed by lactase. Casella discloses that the hydrolysis results in at least 30% hydrolyzed lactose (converted) [col. 3, lines 23-35; col. 4, lines 1-4]. Czarnetsky discloses that whey products can be subjected to both a fermentation process and an enzyme treatment in order to convert carbohydrates such as lactose, in the case of whey, into lactic acid [col. 1, lines 69-72 to col. 2, lines 1-8].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Rodgers and Casella and Czarnetsky before him or her to combine the fermentation and enzymatic processes for converting lactose because Czarnetsky discloses that the two processes can be combined to convert a substantial portion of the lactose in to lactic acid.

Regarding Claims 12-14: Rodgers discloses a method of fermenting whey and the conversion of lactose to lactic acid as discussed above. Rodgers does not disclose converting the lactose by hydrolysis or enzymatic hydrolysis, or that 25% to 99% of the lactose is converted respectively. Casella discloses substituting non fat dry milk with hydrolyzed whey [col.1, lines 50-56, col. 3, lines 15-23], hydrolyzing the lactose with lactase, and that the hydrolysis results in at least 30% hydrolyzed lactose (converted) [col. 3, lines 23-35; col. 4, lines 1-4]. Czarnetsky discloses that whey products can be subjected to both a fermentation process and an enzyme treatment in order to

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convert carbohydrates such as lactose in the case of whey into lactic acid [col. 1, lines 69-72 to col. 2, lines 1-8].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Rodgers, Casella and Czarnetsky before him or her to combine the fermentation and enzymatic processes for converting lactose because Czarnetsky discloses that the two processes can be combined to convert a substantial portion of the lactose into lactic acid.

Regarding Claim 15: Rodgers, Casella, and Czarnetsky disclose as discussed above. None of the references disclose that the hydrolysis of lactose is carried out before the fermentation step.

However, at the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Rodgers, Casella, and Czarnetsky before him or her and based upon what is generally known in the art to first treat the whey with lactase and then to ferment the hydrolyzed whey.

It is known in the art that treating lactose with lactase results in the splitting of lactose into its monosaccharide constituents, galactose and glucose. Further, it is known that glucose is the major sugar used as fuel to produce lactic acid via lactic acid bacteria during lactic acid fermentation. Further Casella acknowledges that the production of glucose due to lactase in hydrolyzed whey and that when hydrolyzed whey is fermented, the pH decreases (production of lactic acid) [col. 3, lines 4-8]. Because treating the lactose contained whey with lactase would have provided an increased amount of glucose in the mixture and because glucose is easily converted to lactic acid by lactic acid fermentation, it would have been obvious to one of ordinary skill in the art to first treat the whey with lactase, followed by lactic acid fermentation.

17. **Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rodgers et al. (US 2,930,696) as applied to claim 11 above and in further view of Sawhill (US 5,643,622).**

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Regarding Claim 20: Rodgers discloses adding propionic acid to fermented whey as discussed above. Rodgers does not disclose that after the propionic acid is added the mixture is further mixed or emulsified or homogenized or sterilized. Sawhill discloses a feed supplement made from whey which includes propionic acid as a feed ingredient and that after adding the propionic acid, the mixture is mixed [col. 9, lines 53 and 61-67; col. 10, lines 46-51].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Rodgers and Sawhill before him or her to mix the propionic acid after adding in order to get the full benefit of mold and bacteria inhibition by distributing the inhibitor throughout the entire product.

18. **Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodgers et al. (US 2,930,696) as applied to claims 1 and 19 above and in further view of Sawhill (US 4,081,155).**

Regarding Claims 22 and 24: Rodgers discloses the concentrated food product of claim 1. Rodgers does not disclose that the food product is diluted and storage stable. Sawhill '155 discloses diluted and storage stable whey product for feeding calves [col. 5, lines 19-24, 42-46; col. 6, lines 23-43, col. 7, lines 39-45].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Rodgers and Sawhill '155 before him or her to provide for a storage stable whey concentrate in order to provide a safe and ready to use nutrient source for calves.

Additionally, Examiner notes that claim 24 is a recitation of the intended use of the claimed invention and in order to patentably distinguish the claimed invention from the prior art, the recitation must result in a structural difference between the claimed invention and the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

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Regarding Claim 23: Rodgers discloses the concentrated food product of claim 1.

Rodgers does not disclose that the dry matter content of the food is 8% to 22%. Sawhill '155 discloses a diluted storage stable whey product that is diluted to 50% to 90% which is indicative of a dry matter content of 10 to 40% [col. 5, lines 42-46].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Rodgers and Sawhill '155 before him or her to provide a dry mater content as discussed above in order to provide a liquid concentrate that is protective of microorganism in the calves' rumen [col. 5, lines 42-46].

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FELICIA C. KING whose telephone number is (571)270-3733. The examiner can normally be reached on Mon- Thu 7:30 a.m.- 5:00 p.m.; Fri 7:30 a.m. - 4:00 p.m. alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer McNeil can be reached on 571-272-1540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/F. K./

Examiner, Art Unit 1784

/Timothy M. Speer/

Primary Examiner, Art Unit 1784